# 510(k) Summary
**[As Required by 21 CFR 807.92(c)]**

JUN 07 2013

**510(k) Owner:** Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

**Official Contact:** Melissa S. Gonzalez
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**Date Summary Prepared:** March 14, 2013

**Trade Name:** *Intuitive Surgical® da Vinci® Single-Site™* Instruments and Accessories

**Common Name:** *Endoscope and accessories*

**Product Code:** NAY, GCJ

**Classification:** *Endoscope and Accessories, 21 CFR 876.1500*

**Predicate Devices:**

- *Intuitive Surgical® da Vinci® Single-Site™* Instruments and Accessories (K112208/K120215/K122532)

**Device Description:**
The *da Vinci Single-Site* Instruments and Accessories consist of semi-rigid shaft instruments, two fixed-shape curved cannulae (250 mm and 300 mm lengths), an accessory cannula for insertion of manual laparoscopic instruments, a semi-rigid blunt obturator (250 mm and 300 mm lengths), and a *Single-Site* Port (with insufflation tubing and stopcock) for the placement and insertion of multiple cannulae/instruments through a single incision.

The *da Vinci Single-Site* Instruments and Accessories include instruments to perform manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery and suturing. The *da Vinci Single-Site* Instruments and Accessories are intended to be used with the existing *da Vinci Si* Surgical System (IS3000).

**Intended Use:**

The *Intuitive Surgical® da Vinci® Single-Site™* Instruments and Accessories used with the *da Vinci® Si* Surgical System (IS3000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the *da Vinci Single-Site* Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, flexible blunt obturators, and the 5 mm *Single-Site* Port.

The indications for use are unchanged from the predicate.

**Technological Characteristics:**
The only change to the cleared *da Vinci Single-Site* Instruments and Accessories is the addition of the *Single-Site* Permanent Cautery Hook. The *Single-Site* Permanent Cautery Hook is a modified version of the cleared *Single-Site* Monopolar Cautery instrument that incorporates a permanently attached cautery hook, as well as design elements from the *Single-Site* Gen2 instruments cleared under K120215. The modified instrument design is intended to improve ease of assembly and reduce manufacturing costs. The *Single-Site* Permanent Cautery Hook is equivalent to the predicate *Single-Site* Monopolar Cautery instrument in terms of its technological characteristics, and the intended use is identical.

**Performance Data:**
Bench and animal testing demonstrated that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. The differences do not raise any different issues of safety or effectiveness as compared to the predicate devices.

**Summary:**
Based on the intended use, indications for use, technological characteristics, and performance data, the Permanent Cautery Hook is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 7, 2013

Intuitive Surgical, Inc.
% Ms. Melissa Gonzalez
Sr. Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K130726
Trade/Device Name: Intuitive Surgical da Vinci Single-Site Instruments and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY, GCJ
Dated: May 2, 2013
Received: May 6, 2013

Dear Ms. Gonzalez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions/Warnings/Contraindications section of the device's labeling:

> The safety and effectiveness of this device for use in the performance of general laparoscopic abdominal surgery or general gynecological surgery procedures have not been established. This device is only intended to be used for single incision laparoscopic cholecystectomy, benign hysterectomy, and salpingo-oophorectomy with the da Vinci Single Site Instruments and the da Vinci Si Surgical System (IS3000).

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara A. Zimmerman for

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number if known:

Device Name: *da Vinci® Single-Site™* Instruments and Accessories

**INDICATIONS FOR USE:**

The *Intuitive Surgical® da Vinci® Single-Site™* Instruments and Accessories used with the *da Vinci® Si* Surgical System (IS3000) are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the *da Vinci Single-Site* Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, flexible blunt obturators, and the 5 mm *Single-Site* Port.

Prescription Use _X_ AND/OR Over-the-Counter Use _____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K130726